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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/682,838	10/23/2001	David J. Lockhart	3370.1	9173

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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/682,838	LOCKHART ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2003 and 13 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16 and 28-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-16 and 28-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>0303</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: |

FINAL ACTION

1. This action is in response to papers filed 4 March 2003 in which claim 12 was amended and claims 1 and 17-27 were canceled and further in response to papers filed 13 March 2003 in which claim 2 was amended, claim 3 was canceled.

All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 25 September 2002 under 35 U.S.C. 102(b) as being anticipated by Rava et al are withdrawn in view of the amendments. The previous rejections under 3 U.S.C. 102(e) as being anticipated by Schembri et al and under 35 U.S.C. 103(a) as being obvious over Schembri et al in view of Rava are maintained.

All of the arguments have been thoroughly reviewed and are discussed below as they apply to the pending rejections.

Claims 2, 4-16 and 28-33 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

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designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 2, 4-9, 12, 14, 16 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Schembri et al (us[6,258,593 B1, filed 30 June 1999).

Regarding Claim 2, Schembri et al disclose an apparatus for processing a plurality of microarray disposed on a substrate comprising: a containing member constructed and arranged to contain the substrate (i.e. base, Fig.1, #1) ; and a separating member (i.e. cover comprising a lip of the cover, Column 11, line11-19 and Fig. 2 # 8) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 10, line 57-Column 11, line 37 and Fig. 1 & 2 and Claims 1-18) wherein the containing members include a first segment (i.e. housing, Fig. 1, #5) and a second segment (i.e. base, Fig. 1, #1) in contact with the first segment wherein the substrate is disposed between the first and second segments (Column 11, lines 9-37 and Fig. 1).

Regarding Claim 4, Schembri et al disclose the apparatus wherein the separating member is disposed between the first and second segments when the separating member is in the first position and is disposed apart from the first and second segments when the separating member is in the second position (Fig. 1).

Regarding Claim 5, Schembri et al disclose the apparatus wherein the substrate is retained in place by the first and second segments (Column 11, lines 9-37 and Fig. 1).

Regarding Claim 6, Schembri et al disclose the apparatus wherein the first segment includes a central frame i.e. base & housing (Column 10, line 57-Column 11, line 37 and Fig. 1).

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Regarding Claim 7, Schembri et al disclose the apparatus wherein the central frame includes an inlet port for receiving fluids and an outlet port for expelling fluids i.e. access ports (Column 11, lines 19-26 and Fig. 1 # 10 & 11).

Regarding Claim 8, Schembri et al disclose the apparatus wherein the separating member includes one or more walls (i.e. lips of the covers, Fig 2 #8) constructed and arranged to fluidically separate the at least two microarrays when the separating member is disposed in the first position (Column 11, lines 38-52 and Fig. 1 #4).

Regarding Claim 9, Schembri et al disclose the apparatus wherein the separating member includes a grid plate (i.e. grid-like arrangement multiple covers for the plurality of arrays, Column 11, lines 26-37).

Regarding Claim 12, Schembri et al disclose the apparatus wherein the microarrays include synthesized probe arrays wherein the probe comprise oligonucleotides (Column 13, lines 40-47).

Regarding Claim 14, Schembri et al disclose the apparatus wherein the plurality of microarrays are disposed on a contiguous surface of the substrate (Column 11, lines 26-37 and Fig. 1).

Regarding Claim 16, Schembri et al disclose an apparatus for processing a plurality of microarrays disposed on a substrate comprising: containing members including a first segments (base) and a second segment (housing) wherein the substrate is disposed between the first and second segments; and a separating member including a grid plate (covers, Fig. 1 #3) having a plurality of grid elements constructed and arranged so that when the separating member is disposed in a first position with respect to the containing member at least two of the plurality of microarrays are fluidically separated from each other by one or more of the grid elements and when the separating member is disposed in a second position, at least two microarrays are fluidically coupled with each other (Column 11, lines 9-52).

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Regarding Claim 28, Schembri et al disclose a microarray processing system comprising a first segment (base); a second segment in contact with the first segment (housing); and a processing array positioned between the first segment and the second segment and retained in place by the first and second segments (Column 11, lines 9-52 and Fig. 1).

Response to Arguments

4. Applicant argues that while Schembri et al teach their reaction chambers microarrays are fluidically separated i.e. sealed, Schembri et al do not teach a second position wherein the microarrays are fluidically coupled. The argument has been considered but is not found persuasive because Schembri et al teach their reactions chambers comprising the plurality of microarrays are reversibly sealed for microarray reading and reaction chamber reuse (Column 8, lines 54-Column 9, line 9 and Example 3, Column 17, line 27-Column 18, line 25). During hybridization, the reaction chamber is sealed and the microarrays are fluidically separated (first position). Following hybridization, the reaction chamber is disassembled (second position), the microarray containing substrates are fluidically coupled in a slide boat for washing. As such, Schembri et al teach the first and second positions as instantly claimed.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 10, 11, 13, 15 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri et al (U.S. Patent No. 6,258,593 B1, filed 30 June 1999) in view of Rava et al (U.S. Patent No. 5,545,531, issued 13 August 1996).

Regarding Claims 10 and 11, Schembri et al teach the apparatus for processing a plurality of microarray disposed on a substrate comprising: a containing member constructed and arranged to contain the substrate (i.e. base, Fig. 1, #1) ; and a separating member (i.e. cover comprising a lip of the cover, Column 11, line 11-19 and Fig. 2 # 8) which is constructed and arranged so that when the separating member is disposed in a first position (i.e. on the substrate) with respect to the containing members, at least two of the microarrays are fluidically separated from each other by the separating member and when the separating member is in a second position with respect to the containing members the at least two arrays are fluidically coupled with each other (Column 10, line 57-Column 11, line 37 and Fig. 1 & 2 and Claims 1-18) wherein the separating member includes a grid plate (i.e. each cover comprising a lip, provides a grid-like over each of the plurality of arrays, Column 11, lines 26-37) wherein the grid elements is equal in number to the plurality of microarrays as recited in Claim 11 (Fig. 1 #3 & #3') but they do not teach the grid plate includes a plurality of grid elements as recited in Claim 10. However, grid plates comprising a plurality of elements were well know in the art at the time the claimed invention was made as taught by Rava et al. who teach a similar apparatus. Their similar apparatus also comprises a containing member and a separating member (Column 8, lines 1-21 and Fig. 4 & 5) and further including a grid plate comprising a plurality of grid elements (i.e. channels) determined by the one or more walls wherein each of the microarrays is fluidically separated from each of the other microarrays by a grid element when the separating member is disposed in the first position (on the substrate) and wherein each of the microarrays is fluidically coupled with each other when the separating member is in the second position wherein the plurality of grid elements is equal in number to the plurality of microarrays (Column 8, lines 1-21 and Fig. 4). Additionally they teach their

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grid plate is convenient because instrumentation already exists for handling and reading assays having their grid plate format (Column 8, lines 44-46). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the grids of Schembri et al with the grid plate of Rava et al based on the fact that instrumentation already exists for handling and reading assays having their grid plate format (Rava, Column 8, lines 44-46) for the obvious benefits of convenience and economy of instrumentation.

Regarding Claim 13, Schembri et al teach the apparatus wherein the microarrays include synthesized probe arrays wherein the probe comprise oligonucleotides (Column 9, lines 16-26 and Column 13, lines 40-47) but they are silent regarding probe synthesis. However, microarrays comprising oligonucleotide probes synthesized using photolithography was well known in the art at the time the claimed invention was made as taught by Rava et al who teach the similar apparatus wherein the oligonucleotides are synthesized to the microarrays based, at least in part, on photolithography wherein the photolithography enable each probe region to occupy a very small area on the support (Column 9, lines 10-27). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the photolithography probe synthesis of Rava et al to the probes of Schembri et al and to synthesize each probe within a very small region as taught by Rava et al (Column 9, lines 16-20) thereby providing a high density microarray for the obvious benefits of analyzing a high number of reactions on a single microarray.

Regarding Claim 15, Schembri et al teach the apparatus wherein the plurality of microarrays are disposed on a contiguous surface of the substrate (Column 11, lines 26-37 and Fig. 1) but they do not teach the contiguous surface comprises a photolithographic wafer (Column 9, lines 13-34 and 52-60). However, microarrays comprising contiguous surface comprising a photolithographic wafer was well known in the art at the time the claimed invention was made as taught by Rava et al (Column 9, lines 10-52). Specifically, Rava et al teach the similar apparatus wherein the oligonucleotides are synthesized on contiguous

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surfaces comprising a photolithography wafer using photolithography wherein the photolithography technique enables each probe region to occupy a very small area on the support (Column 9, lines 10-27). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the photolithography probe synthesis on photolithographic wafers of Rava et al to the probes of Schembri et al and to synthesize each probe within a very small region as taught by Rava et al (Column 9, lines 16-20) thereby providing a high density microarray for the obvious benefits of analyzing a high number of reactions on a single microarray.

Regarding Claim 29, Schembri et al the microarray processing system comprising a first segment (base); a second segment in contact with the first segment (housing); and a processing array positioned between the first segment and the second segment and retained in place by the first and second segments (Column 11, lines 9-52 and Fig. 1) wherein the array includes a plate member (substrate) between the first and second segments, wherein the plate member includes a first surface, a grid segment (cover having a lip) and a bottom support segment (base) wherein the grid elements is equal in number to the plurality of microarrays as recited in Claim 11 (Fig. 1 #3 & #3') wherein the grid segments is disposed in a first position between the bottom support segment and the plate member forming a chamber that includes a surface portion (Fig. 1) but they do not teach the grid plate includes a plurality of grid elements as recited in Claim 10. However, grid plates comprising a plurality of elements were well know in the art at the time the claimed invention was made as taught by Rava et al. who teach a similar apparatus. Their similar apparatus also comprises a containing member and a separating member (Column 8, lines 1-21 and Fig. 4 & 5) and further including a grid plate comprising a plurality of grid elements (i.e. channels) determined by the one or more walls wherein each of the microarrays is fluidically separated from each of the other microarrays by a grid element when the separating member is disposed in the first position (on the substrate) and wherein each of the microarrays is fluidically coupled with each other when the separating

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member is in the second position wherein the plurality of grid elements is equal in number to the plurality of microarrays (Column 8, lines 1-21 and Fig. 4). Additionally they teach their grid plate is convenient because instrumentation already exists for handling and reading assays having their grid plate format (Column 8, lines 44-46). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the grids of Schembri et al with the grid plate of Rava et al based on the fact that instrumentation already exists for handling and reading assays having their grid plate format (Rava, Column 8, lines 44-46) for the obvious benefits of convenience and economy of instrumentation.

Regarding Claim 30, Schembri et al teach the apparatus comprising a grid seal between the plate member and the grid segment and a second grid seal between the grid segment and the bottom support segment i.e. screws which when tightened seals the housing to the base (Column 11, lines 38-52 and Fig. 1 #13).

Regarding Claim 31, Schembri et al teach the apparatus wherein a plurality of microarrays are disposed on the first surface of the plate member and when the grid segment is disposed in the first position, the multiple processing chambers align with and fluidically separate the plurality of microarrays (Column 11, lines 26-36).

Regarding Claim 32, Schembri et al teach the apparatus wherein the grid segment is moveable between the first position and a second position in which the multiple processing chambers are not aligned with the plurality of microarrays i.e. the apparatus is disassembled following hybridizations and when disassembled, the chambers are not aligned with the microarrays (Column 9, lines 2-9 and Column 17, line 28-Column 18, line 25).

Regarding Claim 33, Schembri et al teach the apparatus wherein the grid segment is moveable between the first position and a second position in which the multiple processing chambers do not fluidically separate the plurality of microarray i.e. the apparatus is disassembled following hybridizations and when disassembled, the chambers are not aligned with the microarrays (Column 9, lines 2-9 and Column 17, line 28-Column 18, line 25).

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Response to Arguments

7. Applicant reiterates the arguments discussed above regarding the fluidically coupled second position. The arguments have been considered but are not found persuasive for the reasons stated above i.e. Schembri et al specifically teach the fluidically coupled second position (Example 3).

Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kreek et al (U.S. Patent Application No. 2001/0053849 A1, filed 16 June 1999) disclose an apparatus for processing a plurality of microarrays.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
June 4, 2003